Dräger medical
A Dräger and Siemens Company

Jaundice Meter

Konica Minolta/Dräger Medical

WARNING:
For a full understanding of the performance characteristics of this equipment, the user should carefully read this manual before operating.

Model JM-103
Operating Instructions

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Section 1
Symbol Definition and Intended Use

Symbol Definition

This manual contains different typefaces and icons designed to improve readability and increase understanding of its content. Note the following examples:

- Standard text—used for regular information.
- **Boldface text**—emphasizes a word or phrase.
- **NOTE:**—sets apart special information or important instruction clarification.
- The symbol below highlights a WARNING or CAUTION:

Warning and Caution

  - A WARNING identifies situations or actions that may affect patient or user safety. Disregarding a warning could result in patient or user injury.
  - A CAUTION points out special procedures or precautions that personnel must follow to avoid equipment damage.

- The symbol below highlights a type BF applied part:

Type BF Applied Part

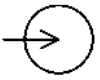
  - The instrument provides a specified degree of protection against electric shock, particularly the leakage current and reliability of the protective ground connection with an F-type applied part. An F-type applied part indicates an applied part isolated from all other parts of the instrument to such a degree that the patient leakage current allowable in a single-fault condition is not exceeded when a voltage equal to 1.1 times the highest-rated mains voltage is applied between the applied part and ground.

- The symbol below highlights an ELECTRICAL SHOCK HAZARD WARNING:

Electrical Shock Hazard Warning

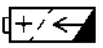
- The symbol below indicates INPUT RATING:

Input Rating Symbol



- The symbol below indicates that the product uses a RECHARGEABLE BATTERY:

Rechargeable Battery Symbol



- The symbol below indicates RESET:

RESET Button Symbol

- The symbol below, when applied to the device, indicates:

ATTENTION: Consult Accompanying Documents

Intended Use

⚠ CAUTION:

Magnetic Resonance Imaging (MRI) procedures interfere with Jaundice Meter operation. Inaccurate readings could occur.

⚠ CAUTION:

Do not use a mobile telephone when using the Jaundice Meter. A measurement error could occur.

Intended Use of the Jaundice Meter

The Jaundice Meter (JM-103) is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants.

The device is intended for use in hospitals or doctors' offices under a physician's supervision or at their direction to assist clinicians in monitoring of newborn infants. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements.

Newborn infants whose Jaundice Meter (JM-103) test results are indicative of hyperbilirubinemia should be evaluated by their physician(s) for appropriate patient management. Specific neonatal patient bilirubin levels should be confirmed by other methods, such as serum bilirubin, prior to treatment determinations.

The Jaundice Meter (JM-103) is not intended for home use.

Limitations (Doctors' Office Use)

Use only on infants up to 14 days of age.

For doctors' office application, use only the sternum location when taking measurements.

Please be aware, performance in doctors' offices may vary from performance in hospitals.

Precocious Jaundice

Do not use this device on infants with precocious jaundice. If there is a possibility that the infant is suffering from precocious jaundice, as a result of an incompatible blood type or hemolytic jaundice, it is recommended that the total serum bilirubin be measured.

Intended Use of the User Manual

This manual provides instructions for installation, use, operator maintenance, and troubleshooting of the Jaundice Meter (JM-103). Konica Minolta/Dräger Medical cannot be responsible for the performance of the Jaundice Meter if the user does not operate the unit in accordance with the instructions, fails to follow maintenance recommendations, or makes any repairs with unauthorized components. Only qualified service personnel should perform repair.

Section 2
Introduction, Features, and Specifications

Introduction

To prevent kernicterus in newborn infants, it is very important to detect jaundice in its early stages. The Jaundice Meter (JM-103) is a non-invasive transcutaneous bilirubinometer. This hand-held device allows a quick, non-invasive estimate of bilirubin concentration, to be used as an aid for the management of jaundice in newborn infants. The measurements are taken automatically when you place the instrument's measuring probe against the measuring site of the infant and press it gently; the measured value is then displayed.

Measuring Point

Measurements must be taken only on the infant's forehead (at hospital sites only) or sternum (at hospital sites or physicians' offices) where a sufficient amount of blood is circulated. A possibility exists that the bilirubin in the subcutaneous tissue may measure low for areas with minimal blood flow or areas in which the subcutaneous tissue is subject to keratinization.

Although correlation with serum bilirubin was observed for both forehead and sternum measurements, the clinical studies performed with the Jaundice Meter (JM-103) show consistently better results with measurements taken at the sternum versus the forehead. There is a possibility that this difference may be more pronounced for infants that have been exposed to sunlight, such as infants seen at doctors' offices. Only sternum measurements were evaluated during the studies conducted at doctors' offices; correlation of forehead measurements with serum bilirubin has not been evaluated, and the device is not intended for forehead measurements at doctors' offices. **Therefore, use the sternum location when taking measurements at doctors' offices.**

Phototherapy

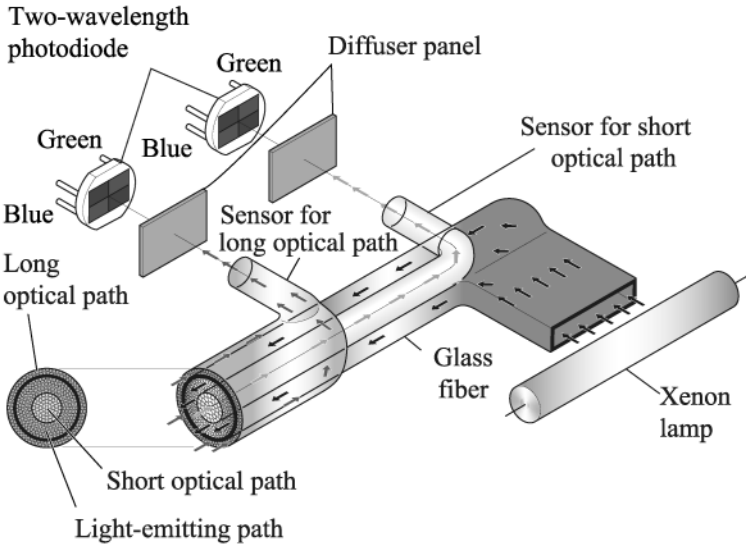
⚠ WARNING:

Do **not** use the Jaundice Meter after initiation of phototherapy or after an exchange transfusion as results may be inaccurate under these conditions. Patient injury could occur.

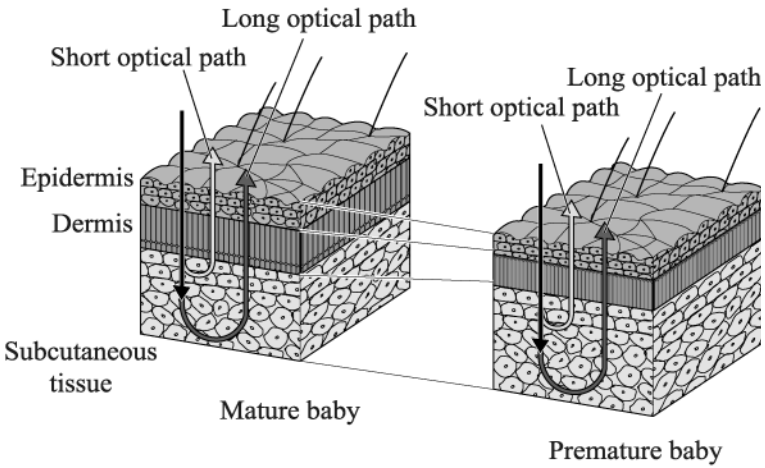
Explanation of the Test

Measuring Principle

The Jaundice Meter determines the yellowness of an infant's subcutaneous tissue by measuring the difference in the optical densities for light in the blue (450 nm) and green (550 nm) wavelength regions. The measuring probe has two optical paths. This method allows for a more precise measurement of yellowness in an infant's subcutaneous tissue by minimizing the influences of the melanin pigment and the skin maturity.



When the measuring probe is pressed against the forehead or sternum of the infant, the built-in xenon lamp flashes. The light from the xenon lamp passes through the glass fiber and illuminates the skin. The light scatters and is absorbed in the skin and subcutaneous tissue repeatedly, and then finally returns to the sensor side of the glass fiber. Of the light that returns, the part scattered from the shallow areas of the subcutaneous tissue passes through the inner core, or short-optical path, of the fiber. The part scattered from the deep areas of the subcutaneous tissue passes through the outer core, or long-optical path, and then reaches its corresponding photodiode.



By calculating the difference in the optical densities, the parts that are common to the epidermis and dermis are deducted, and as a result, the difference in the optical densities between the two wavelength regions can be obtained for the subcutaneous tissue only. Since the optical density difference shows a linear correlation with the total serum bilirubin concentration, it is converted to the estimated bilirubin concentration and is indicated digitally.

The Jaundice Meter (JM-103) device software uses a correlation coefficient to convert the measurement difference from the dual optical path to an estimated bilirubin concentration. The calculation formula used includes the correlation coefficients α and γ. These coefficients were determined in pre-clinical testing. The equation used is as follows:

$$J_{sample} = \alpha(L\text{-}S) + \gamma$$

Where L and S are the long and short optical path measurements.

Use of the Device

Patient Population

The Jaundice Meter (JM-103) is indicated for use in neonatal patients born >35 weeks gestation who have not undergone transfusion or phototherapy treatment.

Averaging of Measurements

Averaging measurements may allow for more precise results. Assess the advantages of using average measurements at your facility. There was no significant difference between the averaged measurements and the single measurement approaches in the largest study for sternum measurements. The mean of three measurements showed the highest degree of correlation (r=0.965), however, the difference was minimal with a single measurement (r=0.963).

Averaging was not evaluated in the physicians' office study.

Action Levels

Each facility should determine their own action levels based on studies of performance of the device on their population. Appropriate action levels may vary depending on performance of the device, such as precision or correlation with serum bilirubin, in the hands of the user. Some factors that could affect performance of the device or appropriate action levels include skin color, age, or measurement site. The bias relative to serum bilirubin differs between hospital versus physicians' office sites (see Appendixes A and B). Different action levels may be appropriate for hospital versus physicians' offices. **Careful selection of action levels should be made so that false negatives do not prevent appropriate follow up measures.**

Calibration

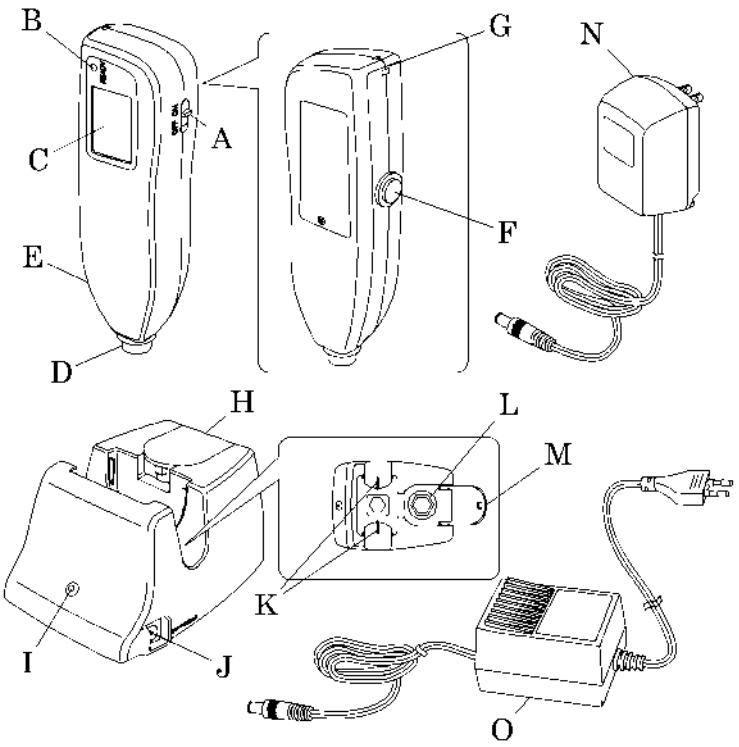
There is no user calibration of this device. The system does include a checker that measures the intensity of light from the device to ensure the light output is acceptable for proper use.

Processing of Measured Values

The Jaundice Meter (JM-103) determines the yellowness of the subcutaneous tissue by measuring the difference in the optical densities for light in the blue and green wavelength regions. The optical density difference has been shown to have a linear correlation with serum bilirubin concentration. The device computes an estimated bilirubin concentration based on this linear correlation and provides the value on the display.

Features

Controls, Indicators, and Connections

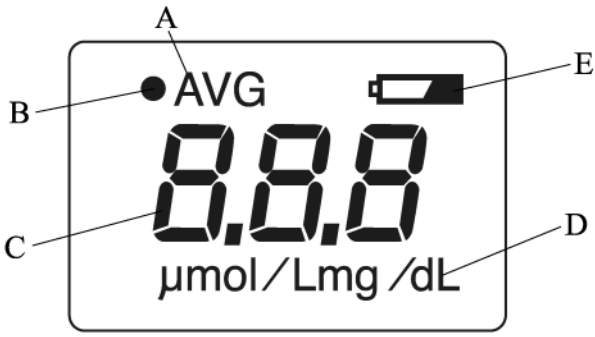


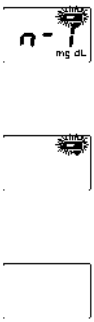
Controls, Indicators, and Connections

	Name	Function
A	**Power** switch	Turns the Jaundice Meter on and off. When used with the **Reset** button, the device switches to Check Mode and changes the unit of measurement.
B	**Ready** lamp	Illuminates to indicate that the Jaundice Meter is ready for the next measurement.
C	Display	Displays the measured value.
D	Measuring probe	Takes the measurement when pressed against the measuring point.

	Name	Function
E	Charger section	Connect the charger unit to the charger section.
F	**Reset** button	Deletes the currently displayed measured value and prepares for the next measurement. When used with the **Power** switch, the device switches to Check Mode and changes the unit of measurement.
G	Strap attachment area	Is where the strap attaches.
H	Checker cover	Open this checker cover to check the Jaundice Meter.
I	Charger lamp	Illuminates to indicate that the Jaundice Meter is charging.
J	DC jack	Connect the AC adapter to this jack.
K	Charger jack	Connect the main body to this jack.
L	Checker	Checks for the intensity of light output by taking measurements in Check Mode.
M	Standard checker values	For reference.
N	DC plug	Connect the charger's DC jack to this.
O	DC Plug (international)	Connect the charger's DC jack to this.

Display



	Name	Function
A	AVG	Illuminates during averaging measurement.
B	Optical path indicator (•)	When verifying light output with the checker, (•)illuminates when the L-value appears and extinguishes when the S-value appears.
C	Value	Displays the measured value. **NOTE**: When the measured value is greater than 20 mg/dl, the display shows "---" and the physician should be contacted.
D	Unit of measurement	Displays the unit of measurement in either milligrams per deciliter (mg/dL) or micro-moles of solute per liter (µmol/L)
E	Battery indicator 	When the battery power is low, the battery indicator blinks. Charge the battery as soon as possible (see "Charging the Battery" on page 4-1). If **only** the battery indicator lights, the battery has run out. Go to "Charging the Battery" on page 4-1. If the power is on and the display is blank, the battery is completely exhausted. Go to "Charging the Battery" on page 4-1.

Standard Features

- Jaundice Meter (JM-103)
- Charger unit (Model JM-A30) with a checker
- AC adapter (Model JM-A31)
- Carrying case and wrist strap

Specifications

Standard Features

Feature	Dimension
Model name	JM-103
Measuring method	Determines the yellowness of the subcutaneous tissue by using two optical paths to measure the optical density difference at two wave-lengths
Measurement range	0.0 mg/dL to 20 mg/dL or 0 µmol/L to 340 µmol/L
Clinical Data Standard Error of Estimate (SEE) *	± 1.5 mg/dL or ± 25.5 µmol/L
Light source	Pulse xenon arc lamp
Light source life	150000 measurements
Sensors	Silicon photodiodes
Power source	2.4 V, Special Ni-MH battery
Protection type and level	Internally-powered instrument, BF-type
Minimum number of measurements when fully charged	400 single measurements
Operating temperature range	10°C (50°F) to 40°C (104°F)
Operating relative humidity range	30% to 95% non-condensing
Storage temperature range	-10°C (14°F) to 50°C (122°F)
Storage relative humidity range	30% to 95% non-condensing
Dimensions	48 mm (1.9") wide x 15.5 cm (6.1") high x 33 mm (1.3") deep
Weight, including battery	150 g (5.3 oz)
AC adapter input for North America	120V, 50/60 Hz, 10 W
AC adapter input for international use (old)	200V-240V, 50/60 Hz, 12.5VA
AC adapter input for international use (new)	100V-240V, 50/60 Hz, 0.14-0.07A
AC adapter output	9V, 500 mA, 4.5W

*The standard deviation shown above is based on the average of the

clinical data available. On average, 66% of results fall within this range, and the remainder fall outside this range. This value can be affected by variables such as age, skin color, and preformance of the device in the hands of the user. Refer to Appendixes A and B for a detailed description of results by clinical site, measurement location, and patient demographics. The SEE shown above are based on the clinical data available and can be affected by variables such as infant developmental age, ethnicity, etc. Therefore, we recommend that the JM-103 be used in conjunction with other clinical signs and laboratory measurements. "Specific Bilirubin Measurement" should be confirmed by other methods such as laboratory blood serum analysis.

Regulations, Standards, and Codes

In North America
With respect to electrical shock, fire, and mechanical hazards only, this instrument complies with UL 60601-1 and CAN/CSA C22.2 No. 601.1.

In Europe, this instrument complies with EN60601-1, EN60601-1-2, and EN ISO13485, and EN ISO14971.

Directive 2002/96/EC of the *European Parliament and of the Council of 2003-01-27 on Waste Electrical and Electronic Equipment (WEEE) Annex IV, prEN 50419* applies.

Device Classification

The Jaundice Meter (JM-103) meets the requirements for the following classifications:

- Protection against electrical shock: Internally powered
- Type of applied part: BF
- Degree of protection against harmful ingress of water: Not applicable
- Not suitable for use in the presence of flammable anesthetic mixture with air or oxygen or nitrous oxide.
- Mode of operation of equipment: Continuous while in use (IEC 60601-1)

Electromagnetic Compatibility (EMC) Guidance and Manufacturer's Declarations

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The Jaundice Meter (JM-103) is intended for use in the electromagnetic environment specified below. The customer or user of the unit should ensure that the unit is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment—Guidance**
Radio frequency (RF) emissions —CISPR 11	Group 1	The Jaundice Meter (JM-103) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference with nearby electronic equipment.
RF emissions—CISPR 11	Class B	The Jaundice Meter (JM-103) is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions—IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions—IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The Jaundice Meter (JM-103) is intended for use in the electromagnetic environment specified below. The customer or user of the unit should ensure that the unit is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
Electrostatic discharge (ESD)—IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	The floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst—IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge—IEC 61000-4-5	± 1 kV differential mode	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The Jaundice Meter (JM-103) is intended for use in the electromagnetic environment specified below. The customer or user of the unit should ensure that the unit is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
Voltage dips, short interruptions, and voltage variations on power supply input lines—IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 seconds	< 5% U_T (> 95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the unit requires continued operation during power mains interruptions, it is recommended that the unit be powered from an uninterruptable power supply or battery.
Power frequency (50/60 Hz) magnetic field—IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to the application of the test level.			

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The Jaundice Meter (JM-103) is intended for use in the electromagnetic environment specified below. The customer or user of the unit should ensure that the unit is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance Recommended Separation Distance**
Conducted RF—IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the Jaundice Meter (JM-103), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance**
Radiated RF—IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The Jaundice Meter (JM-103) is intended for use in the electromagnetic environment specified below. The customer or user of the unit should ensure that the unit is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance Recommended Separation Distance**

NOTE:
At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE:
These guidelines may **not** apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. Field strengths from fixed transmitters, such as base stations for radio, cellular/cordless telephones, land-mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed-RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the unit is used exceeds the applicable RF compliance level, observe the unit to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the unit.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be < 3 V/m.

NOTES:

Section 3
Precautions and Safety Tips

Precautions

⚠ WARNING:

Do not use the instrument in areas where flammable or combustible gases, such as anesthetic gases, are present. Doing so could result in a fire. Personal injury or equipment damage could occur.

⚠ WARNING:

If the instrument, the charger unit, or the AC adapter are damaged, or if smoke or an odd smell occurs, do **not** use the instrument, the charger unit, or the AC adapter. In such situations, immediately turn off the instrument, unplug the AC adapter from its power source, and contact the nearest authorized service facility. Failure to do so could result in fire, personal injury, or equipment damage.

⚠ WARNING:

Do **not** use the Jaundice Meter after initiation of phototherapy or after an exchange transfusion as results may be inaccurate under these conditions. Patient injury could occur.

SHOCK HAZARD:

Always plug the instrument into an AC outlet of the correctly rated voltage and frequency. Failure to do so could result in fire, personal injury, or equipment damage.

SHOCK HAZARD:

Do not disassemble or modify the instrument, the charger unit, or the AC adapter. Fire, personal injury, or equipment damage could occur.

⚠ CAUTION:

Do not place the instrument on an unstable or sloping surface. The instrument or charger unit could drop or overturn. Equipment damage could occur.

⚠ CAUTION:

Do not use the instrument in direct sunlight. Equipment damage could occur.

⚠ CAUTION:

The Jaundice Meter is a precision instrument. When using it, do **not** drop it, expose it to shocks or strong vibrations, or place heavy objects on it. Equipment damage could occur.

⚠ CAUTION:

Do not allow blood or other liquids to come in contact with the instrument. Should blood or other liquids come in contact with the instrument, immediately clean the instrument (see “Cleaning” on page 6-1). Failure to do so could result in equipment damage.

⚠ CAUTION:

The instrument has a built-in, non-user-replaceable battery. Do **not** disassemble the instrument to replace the battery. To replace the battery, contact your dealer or authorized service center. Failure to do so could result in equipment damage.

Electromagnetic Compatibility Precautions

General information on electromagnetic compatibility (EMC) according to the international EMC standard IEC 60601-1-2: 2001

Pins of connectors identified with the ESD warning symbol shall not be touched and not be connected unless ESD precautionary procedures are used. Such precautionary procedures may include antistatic clothing and shoes, the touch of a ground stud before and during connecting the pins or the use of electrically isolating and antistatic gloves. All staff involved in the above shall receive instruction in these procedures.

NOTE:
Portable and mobile RF communications equipment can affect medical electrical equipment.

NOTE:
Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the technical documentation available from Dräger Service upon request.

Safety Tips

⚠ WARNING:

This instrument emits intense light to take its measurements. Take measurements only at the forehead or sternum (hospital application). Doctors' office use should be performed at the sternum only. Do not press the measuring probe when it is directed toward the infant's or caregiver's eyes. Damage to the eyes could occur.

⚠ WARNING:

Before use, clean the measuring probe by wiping it with medicinal alcohol. Failure to do so could result in the spread of infection or infant injury.

⚠ WARNING:

The charger unit (JM-A30) and the AC adapter (JM-A31) are solely designed for use with the Jaundice Meter (JM-103). Use them **only** when charging the instrument. Using them to charge other equipment could result in personal injury or equipment damage.

⚠ WARNING:

Only facility-authorized personnel should troubleshoot the Jaundice Meter. Troubleshooting by unauthorized personnel could result in personal injury or equipment damage.

⚠ WARNING:

Follow the product manufacturer's instructions. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

This product has been validated with the accessories and options listed in this manual and found to comply with all relevant safety and performance requirements applicable to the device. It is therefore the responsibility of that person or organization who makes an unauthorized modification, or incorporates an unapproved attachment to the device, to ensure that the system still complies with those requirements. [IHA036]

SHOCK HAZARD:

Do not plug or unplug the AC power cord's plug with wet hands. Personal injury or equipment damage could occur.

SHOCK HAZARD:

Before cleaning, maintenance, or parts replacement, unplug the charger unit from its power source. Failure to do so could result in personal injury or equipment damage.

SHOCK HAZARD:

Do not expose the unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.

CAUTION:

Do not use harsh cleansers/detergents, such as scouring pads and heavy duty grease removers, or solvents, such as toluene, xylene, and acetone. Equipment damage could occur.

Warning and Caution Labels

WARNING
RISK OF FIRE: DO NOT USE THIS INSTRUMENT IN PLACE WHERE CONBUSTIBLE GASES (ANESTHETICS,ETC.) ARE PRESENT.
RISK OF ELETRIC FIRE: DO NOT MODIFY OR DISASSEMBLE THIS INTRUMENT.
CAUTION
HIGH INTENSITY FLASH. USE ONLY ON RECOMMENDED SKIN LOCATION.

NOTES:

Section 4
Installation and Assembly

Installation

Before using the instrument, charge and inspect the instrument.

Charging the Battery

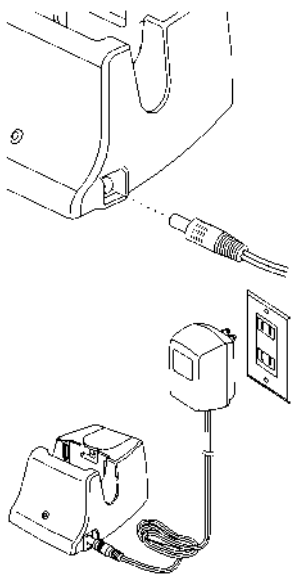
When using the instrument for the first time, ensure that it is fully charged. To maintain a full charge at all times, place the instrument on the charger unit when it is not being used for measurements. When the battery power is low, the **Battery** display blinks.

If the Jaundice Meter is left uncharged for a long period of time, the power of the battery diminishes; ensure that it is charged prior to use. To charge the Jaundice Meter, perform the following:

⚠ WARNING:

The charger unit (Model JM-A30) and the AC adapter (Model JM-A31) are solely designed for use with the Jaundice Meter (JM-103). Use them **only** when charging the instrument. Using them to charge other equipment could result in personal injury or equipment damage.

1. Plug the AC adapter into the **DC** jack of the charger unit. Use only the charger unit and AC adapter supplied with the Jaundice Meter.



NOTE:
The shape of the AC adapter varies according to region.

NOTE:
120V model shown.

SHOCK HAZARD:

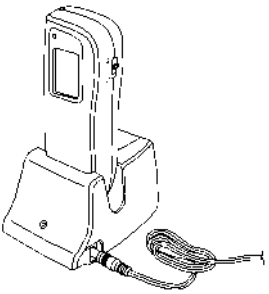
Do not plug or unplug the AC power cord's plug with wet hands. Personal injury or equipment damage could occur.

2. Plug the AC adapter's plug into an AC outlet. Never do so with wet hands.

CAUTION:

Unit must be placed in charger as shown, or damage to charging contacts could occur.

3. **Place the Jaundice Meter on the charger unit so that its display faces you.** When the Jaundice Meter is set on the charger unit properly, the **Charger lamp lights up**.



NOTE:
With a fully charged battery, approximately 400 measurements can be taken.

4. Allow approximately 32 hours for charging to complete.

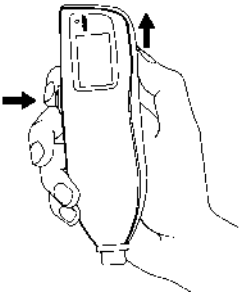
CAUTION:

The instrument has a built-in, non-user-replaceable battery. Do **not** disassemble the instrument to replace the battery. To replace the battery, contact your dealer or authorized service center. Failure to do so could result in equipment damage.

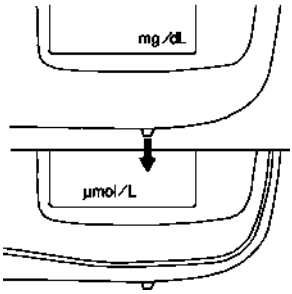
5. To replace the battery, contact your dealer or an authorized service facility.

Selecting the Unit of Measurement

1. Hold down the **Reset** button, and turn on the **Power** switch.Do not release the **Reset** button.

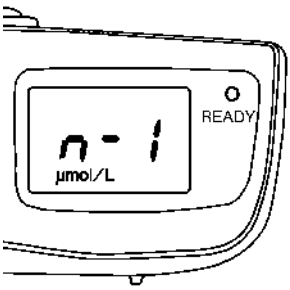


2. While continuing to press the **Reset** button, allow approximately 15 seconds for the unit of measurement to switch from mg/dL to µmol/L, or vice versa.



3. Visually ensure that the unit's display has changed.

4. Release the **Reset** button when unit displays an appropriate unit of measurement. The **Ready** lamp lights up, indicating that the instrument is ready to take a measurement.



5. To change the unit of measurement once more, turn off the **Power** switch, and repeat step 1.

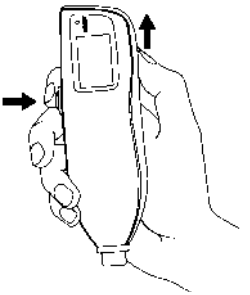
Operational Checkout of the Jaundice Meter

Do not touch the checker's surface in the charging base with your fingers. If the checker gets dirty, wipe it with a soft cloth dampened with alcohol, and then wipe it with a dry cloth. Although the JM-103 device can be damamged as stated on pages 3-1 and 3-4, we recommend the unit always be verified to be operating properly by following the steps as stated in sections 4 and 5. Always remove the unit from service if there are concerns regarding the unit's performance, and immediately contact your Dräger Medical representative.

For quality control purposes, periodically compare the JM-103 to serum bilirubin results. This checks that the instrument maintains consistent performance over time and that the operators are using the instrument properly.

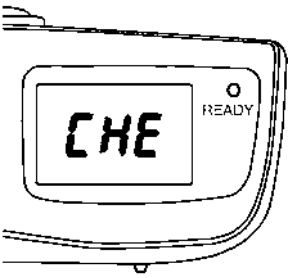
Using the checker supplied with the charger unit, check the instrument to verify that the meter light output is within range for both long and short wavelengths of light. The labeling on the inside cover of the checker will state the acceptance ranges for both long and short wavelengths. The procedure to verify is as follows:

1. Hold the **Reset** button down, and set the **Power** switch to the **On** position.

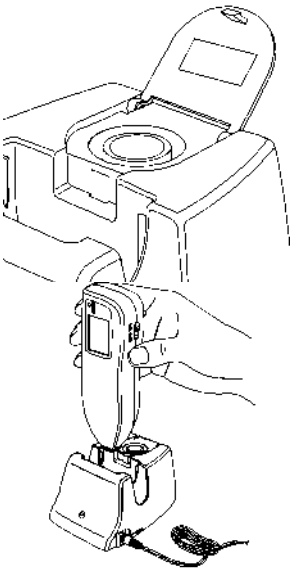


NOTE:
If the **Reset** button is held down for longer than 15 seconds, the unit of measurement switches.

2. After **CHE** appears on the display window, immediately release the **Reset** button. If the **Reset** button is held down for longer than 15 seconds, switch the unit of measurement back to its previous setting (see "Selecting the Unit of Measurement" on page 4-3).
3. Visually confirm that **CHE** appears in the display and that the **Ready** lamp illuminates.

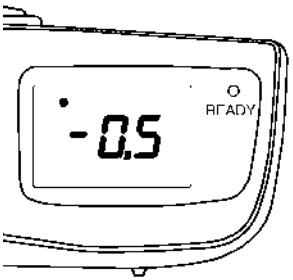


4. Open the cover of the checker. Use only the checker supplied with the Jaundice Meter (JM-103).

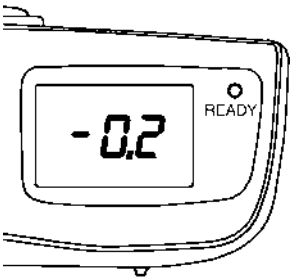


5. Place the measuring probe perpendicular to the checker, and push down gently until a click sounds.
6. If the measuring probe contacts the checker at an angle, place it perpendicular, and take the measurement again.

NOTE:
The display interchanges between the L-value, the measured value of the long-optical path, and the S-value, the measured value of the short-optical path. When the L-value is displayed, "•" appears in the upper left-hand corner of the display.



7. Confirm the measured value. If both the L-value and the S-value are within ± 1.0 of the reference values indicated on the checker cover, the unit is acceptable for use.
8. If the measured value exceeds ± 1.0 of the reference value, perform the following:



a. Clean both the checker and the measuring probe.

b. Place the measuring probe perpendicular to the checker, and push down gently until a click sounds.

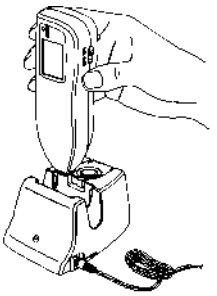
c. If the measured value still exceeds ± 1.0 of the reference value, contact the nearest authorized service facility, and take the unit out of service.

9. Close the cover of the checker.

10. Set the **Power** switch to the **Off** position.

Instructions for Use

Taking Measurements



1. Remove the Jaundice Meter from the charger unit.

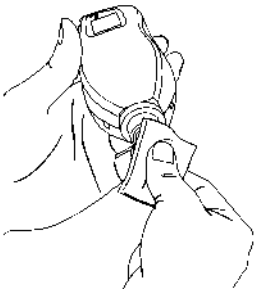
NOTE:
Check the light output of the device at least once each shift (refer to "Operational Checkout of the Jaundice Meter" on page 4-4). Proper light output is one factor that affects meter performance. Light output must be within the range shown on the inside cover of the checker to obtain reliable measurements.

⚠ CAUTION:

Unit must be placed in charger as shown, or damage to charging contacts could occur.

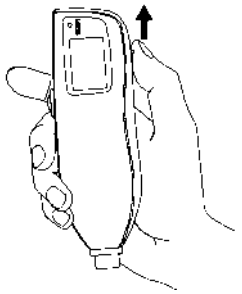
⚠ WARNING:

Before use, clean the measuring probe by wiping it with medicinal alcohol. Failure to do so could result in the spread of infection or infant injury.



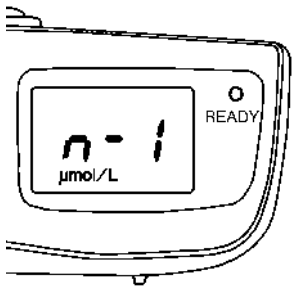
2. Using medicinal alcohol, clean the measuring probe.

3. Set the **Power** switch to the **On** position. The measured value for a single measurement, **n-1**, appears on the display.



NOTE:
The JM-103 is a screening device for Bilirubin in the tissues and should never be used as a stand-alone measurement. Always contact the physician whenever the JM-103 measurements present a concern. The physician will make the determination regarding the laboratory blood serum TSB, as well as other clinical considerations, as these are appropriate measurement for Bilirubin concentration as stated in the indications for use.

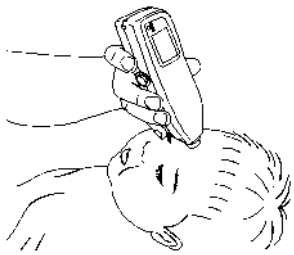
4. Visually check that the **Ready** lamp illuminates.
5. If the battery indicator blinks, charge the battery (see "Charging the Battery" on page 4-1).



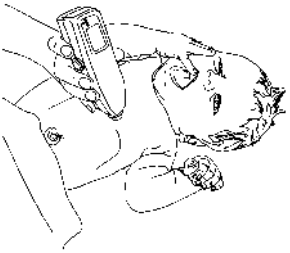
⚠ WARNING:

This instrument emits intense light to take its measurements. Take measurements only at the forehead or sternum (hospital application). Doctors' office use should be performed at the sternum only. Do not press the measuring probe when it is directed toward the infant's or caregiver's eyes. Damage to the eyes could occur.

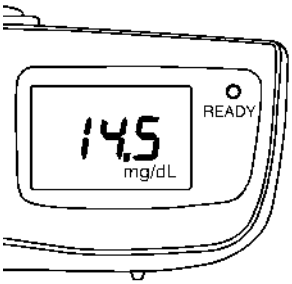
6. Perform the following:
   a. Place the measuring probe vertically against the infant's forehead (at hospital sites only) or sternum (at hospital sites or physicians' offices). Avoid any bruises or discolored areas of the skin.



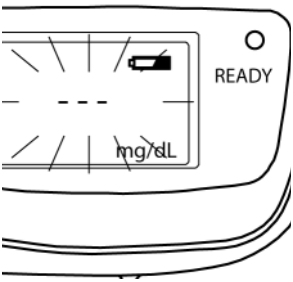
NOTE:
Only use the sternum location for JM-103 measurements when the device is used in a doctor's office.



b. Push the measuring probe gently until a click sounds. The instrument's xenon lamp flashes momentarily, and the measured value appears on the display.



c. If the measured value is outside the measurement range of 20 mg/dL or 340 µmol/L, the display shows "---" and user should contact the physician.



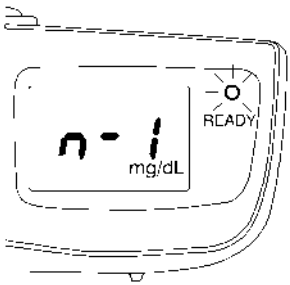
NOTE:
If the instrument is not operated for more than 60 seconds, the backlight on the display goes out.

7. To take another measurement, press the **Reset** button, and continue from step 4.
8. To stop measuring, perform the following:
   a. Set the **Power** switch to the **Off** position.
   b. Using medicinal alcohol, clean the measuring probe.
   c. Place the Jaundice Meter on the charger unit. When the Jaundice Meter is not in use, keep it on the charger unit.

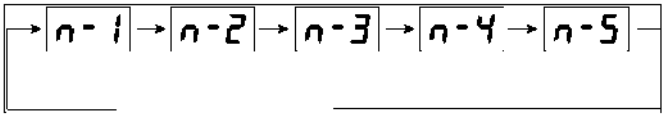
NOTE:
If the caregiver has any concerns regarding the values being presented by the JM 103 for Bilirubin concentration, the physician should be notified immediately for a determination as to whether supportive laboratory blood serum analysis is required or infant retest is appropriate.

Setting the Number of Average Measurements

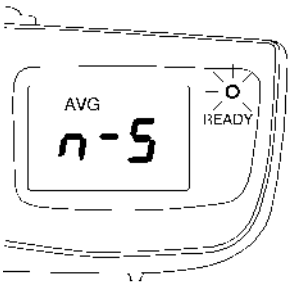
1. Set the **Power** switch to **On** or press the **Reset** button to prepare the instrument for measurement.
   - **n-1**, **n-2**, and so on (up to **n-5**) will appear.



2. Press the **Reset** button for 5 s. The number of average measurements will switch as follows:

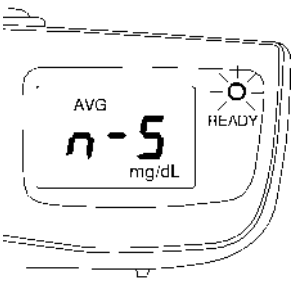


3. Release the **Reset** button when the required number of average measurements is displayed.
   - If **n-2** through **n-5** is selected, **AVG** appears in the upper left corner of the display.
   - The selected number of average measurements will be recorded.



Taking Average Measurements

1. Set the number of average measurements needed.
2. Ensure that the **Ready** lamp is illuminated once **n-5** appears.



NOTE:
n-5 is used in the steps below as an example. The number of measurements you require and set is the number that should appear in the display.

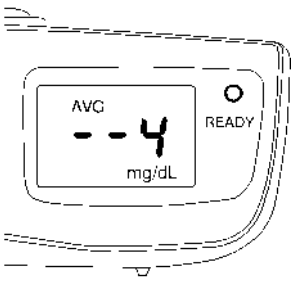
NOTE:
Each measurement must be taken individually by the user. The first measurement is complete when the measuring probe is pressed against the patient and the unit clicks. The probe must then be lifted from the patient and reapplied for the total number of measurements selected (in this example 5 measurements).

⚠ WARNING:

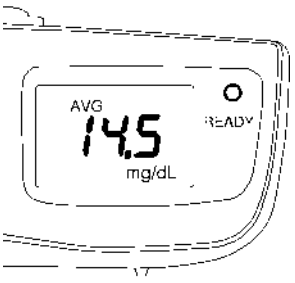
This instrument emits intense light to take its measurements. Take measurements only at the forehead or sternum (hospital application). Doctors' office use should be performed at the sternum only. Do not press the measuring probe when it is directed toward the infant's or caregiver's eyes. Damage to the eyes could occur.

NOTE:
It is recommended that all of the measurements taken for averaging be taken from the same measuring point, forehead (at hospital sites only) or sternum (at hospital sites or physicians' offices).

3. Place the measuring probe vertically on the measuring point, and then apply gentle pressure until the probe clicks.
   - The measurement will be taken, and the number of remaining measurements will be displayed.



4. While ensuring that the **Ready** lamp is illuminated, repeat the measuring until the number of remaining measurements is 0.



- When the remaining number of measurements is completed, the average of the measured values appears in the display.
- If the instrument is left without the preset number of measurements taken, the setting will be canceled without the measurement value being displayed. To set the average measurements again, press the **Reset** button and reset the number of average measurements needed.
- To change the number of average measurements, refer to "Setting the Number of Average Measurements" on page 5-5.

NOTES:

Section 6
Cleaning, Maintenance, Replacement Parts, and Storage and Handling

Cleaning

⚠ WARNING:

Follow the product manufacturer's instructions. Failure to do so could result in personal injury or equipment damage.

SHOCK HAZARD:

Before cleaning, maintenance, or parts replacement, unplug the charger unit from its power source. Failure to do so could result in personal injury or equipment damage.

SHOCK HAZARD:

Do not expose the unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.

⚠ CAUTION:

Do not use harsh cleansers/detergents, such as scouring pads and heavy duty grease removers, or solvents, such as toluene, xylene, and acetone. Equipment damage could occur.

If there is no visible soilage with possible body fluids, we recommend that you clean the unit with alcohol or a medical instrument detergent and warm wet cloth or gauze sponge. If disinfection is desired, you may use a disinfectant as explained in "Disinfecting" on page 6-2. Do not submerge unit in water or hold under running water to rinse.

Steam Cleaning

Do not use any steam cleaning device on the unit. Do not autoclave the unit. Excessive moisture can damage mechanisms or electronics in this unit.

Cleaning Difficult to Access Areas

Do not attempt to disassemble the reader or base for cleaning. Wipe exterior surfaces only. To remove difficult spots or stains, we

recommend that you use a soft bristle brush and alcohol or a medical instrument detergent. To loosen heavy, dried-on soil, you may first need to saturate the spot with a damp gauze sponge or cloth. Disinfecting is preferable in cases of contamination (visual).

Disinfecting

When there is visible soilage and between patients, we recommend that you disinfect the unit with a tuberculocidal disinfectant, such as Kleenaseptic®-b. For customers in the US, the disinfectant should be registered with the Environmental Protection Agency.

Dilute the disinfectant according to the manufacturer's instructions.

Maintenance

There are no user serviceable parts and no maintenance or calibration required. Service is only required if the unit ceases to function as intended or fails the checker reading (see "Operational Checkout of the Jaundice Meter" on page 4-4).

NOTE:
For disposal of consummable materials,see "Disposal" on page 6-3.

Replacement Parts

⚠ CAUTION:

The instrument has a built-in, non-user-replaceable battery. Do **not** disassemble the instrument to replace the battery. To replace the battery, contact your dealer or authorized service center. Failure to do so could result in equipment damage.

There are **no** user-replaceable parts. To replace the battery, contact your dealer or an authorized service facility.

Storage and Handling

When storing the instrument, pay attention to the following conditions:

- Store the instrument at a temperature range of -10°C (14°F) to 50°C (122°F), and at a non-condensing relative humidity range of 30% to 95%.
- Keep the instrument dry.
- Do not store the instrument in locations that may have an adverse effect on its performance, such as:
  - Direct sunlight—do not store near windows.
  - Extreme dust—do not store in closets or bins where dust or lint can gather.
  - Air having salinity or sulphur content.
  - Strong magnetic fields—do not store near MRI or other imaging equipment, and do not store near operating rooms.
- Do not subject the instrument to severe vibration or impact.
- Do not store the instrument in locations where chemicals are stored or where solvent gases may be emitted.
- To ensure no problems will exist the next time the main body and charger are used, thoroughly clean the main body and charger with alcohol, and always store them together.

Disposal

This device is subject to EU Directive 2002/96/EC (WEEE). It is not registered for use in private households, and may not be disposed of at municipal collection points for waste electrical and electronic equipment.

Dräger Medical has authorized a firm to dispose of this device in the proper manner. For more detailed information, please contact your local Dräger Medical organization. (Alternatively: further information can be obtained from our national Dräger Medical organization.)

NOTES:

Section 7
Troubleshooting

Service Calls

When you call technical support about your unit, be prepared to give the serial number from the product identification label. When you give the serial number, the technical support representative can identify your unit and give you the information you need more quickly.

Error Messages

For warnings that may appear on the display window, refer to the table below.

Error Messages

Warning	Cause	Solution
Er1	The measured value is abnormal. In the case of an averaging measurement, the measurement fluctuation is excessively large.	Place the measuring probe perpendicular to the infant's forehead (at hospital sites only) or sternum (at hospital sites or physicians' offices), and take the measurement again. If **Er1** still appears, contact the nearest authorized service facility.
Er2 through **Er6**	A measurement error may have occurred during an averaging measurement, or the hardware is not functioning properly.	Set the **Power** switch to the **Off** position, and then return it to the **On** position. If the warning still appears, contact the nearest authorized service facility.

Troubleshooting

⚠ WARNING:

Only facility-authorized personnel should troubleshoot the Jaundice Meter. Troubleshooting by unauthorized personnel could result in personal injury or equipment damage.

If an abnormality occurs with the Jaundice Meter, perform the following:

1. Refer to the table below, and take the necessary action given.
2. If the abnormality still appears, set the **Power** switch to the **Off** position, and then return it to the **On** position.
3. If the abnormality still continues, contact the nearest authorized service facility, and **take the unit out of service**.

Troubleshooting

Symptom	Possible Cause	Action
The display is blank when the **Power** switch is in the **On** position.	The batteries are exhausted.	Charge the battery (see "Charging the Battery" on page 4-1).
The display suddenly goes blank during a measurement.	The batteries are exhausted.	Charge the battery (see "Charging the Battery" on page 4-1).
The **Charger** lamp does not illuminate when the Jaundice Meter is placed on the charger unit.	The charger unit and the AC adapter are not plugged into an AC outlet correctly.	Plug the charger unit and the AC adapter into an appropriate power source correctly.
	The Jaundice Meter is not placed in the charger unit correctly.	Place the Jaundice Meter perpendicular to the measuring point in the charger unit.
It is impossible to take measurements.	The **Ready** lamp is not illuminated.	Before taking a measurement, ensure that the **Ready** lamp is illuminated.
	The batteries are exhausted.	Charge the battery (see "Charging the Battery" on page 4-1).

Appendix A
Clinical Performance Summary

Introduction

The Jaundice Meter (JM-103) has been the subject of clinical studies in Japan and the United States. The following is a summary review of two clinical studies in the US and a later study in the doctor's office setting.

Because this device performs measurement through the use of light it is non-invasive and painless for the infant. The objective of the clinical studies was to confirm that the device measurement, displayed in units of estimated bilirubin concentration, does correlate with the serum bilirubin concentration sufficiently well to warrant its use as a screening tool.

The data in the following sections is provided to demonstrate results of the JM-103 clinical studies, in comparison to total serum bilirubin. The JM-103 reports values over a range of 0-20 mg/dL estimated bilirubin. Appendix A pages A2 - A18 illustrate results of hospital site studies. Appendix B pages B3 - B8 illustrate results of physicians' office site studies.

The following is a summary of the study protocols:

Study Design

Selection Criteria

The patient selection criteria used for the studies included infants less than 30 days old and weighing greater than 1000 grams. Although the selection criteria was established to be "less then 30 days of age," the infants in the hospital studies would be expected to be primarily NICU and newborn infants unless their medical condition required a longer duration of care. The test was performed on infants who were determined by their physician to require a serum bilirubin test. A tabulation of weight distribution is provided in graph 22 *Infant Weight Distribution*. Error plots by weight are provided in graphs 23 *Clinical Study Site A Birthweight Error Plot, Forehead* and 24 *Clinical Study Site A Birthweight Error Plot, Sternum*.

Demographics of Patient Population

All patients meeting the above criteria were included in the study. There was significant effort to ensure that there was sufficient representation of all skin pigmentation to verify that the JM 103 could be used across all populations with consistent results. The demographics of the patient population included Caucasian, African-American, and other.

Sample Size

The total number of infants in the sample populations are shown on the graphs of the trials presented on pages A-3 through A-15. The hospital trials studies 613 patients. The data for the doctors' office study is in Appendix B and encompassed 201 infants.

Measurement Selection

One study followed a protocol where three measurements were taken, each measurement was recorded and then the three measurements were averaged. The second study took one measurement only. Estimated bilirubin measurements taken during the studies ranged from 1.1 to 20.8 mg/dL. In the doctor's office setting no measurement averaging was performed.

Body Sites Tested

In the hospital setting the measurements were taken on the forehead and sternum each time the measurements were taken for a given patient. In the doctor's office setting all measurements were taken at the sternum.

Number of Hospital Sites

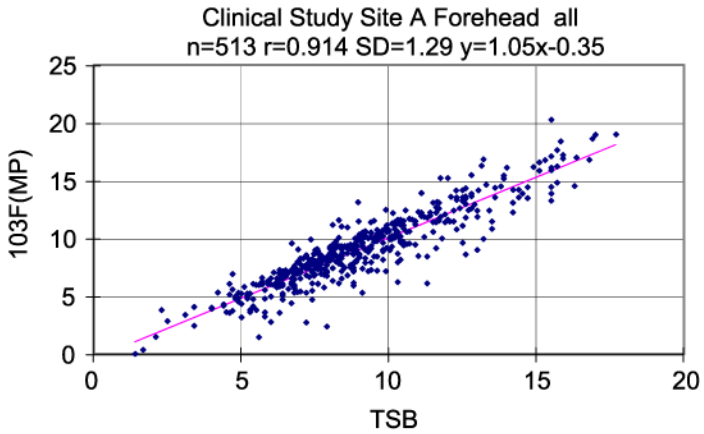
There were two hospital sites that participated in the hospital study. Hospital study site A with 513 patients studied. Clinical study site B with 100 patients studied.

Performance Data

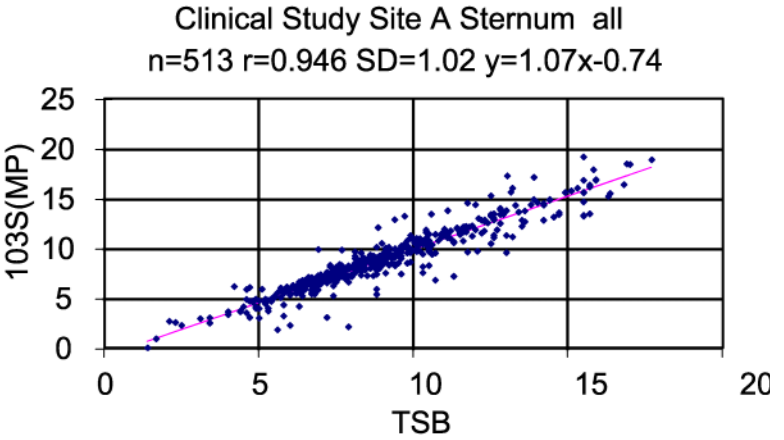
The data in the following sections, as well as Appendix B, is provided to demonstrate the performance of the JM 103. This series of graphs show the correlation of the estimated bilirubin concentration taken non-invasively with the JM 103 to the actual serum bilirubin concentration measured from a blood sample taken from the patient (TSB) as explained in Sections 4 and 5. The device operates over a range of 0.0 –

20.0 mg/dL (0 – 340 µmol/L). The data include graphs in the form of x-y plots where x is the total serum bilirubin concentration measured and y is the JM 103 estimated bilirubin measurement. Refer to the graphics results provided in this appendix for the results of studies at hospital sites. To address device performance in doctors' office setting, a study of 201 infants was performed. Results showed similar performance at doctors' offices as shown in Appendix B. The data for the doctor's office setting contained no forehead measurements as all measurements were taken at the sternum. This data correlated well with prior sternum data (refer to page A-12). The serum bilirubin measurements were taken using direct spectrophotometry in Clinical Study A and specifically with the Beakman-Colter Synchron LX-20by in Hospital Study B. Both systems were used int he doctors' office study as well.

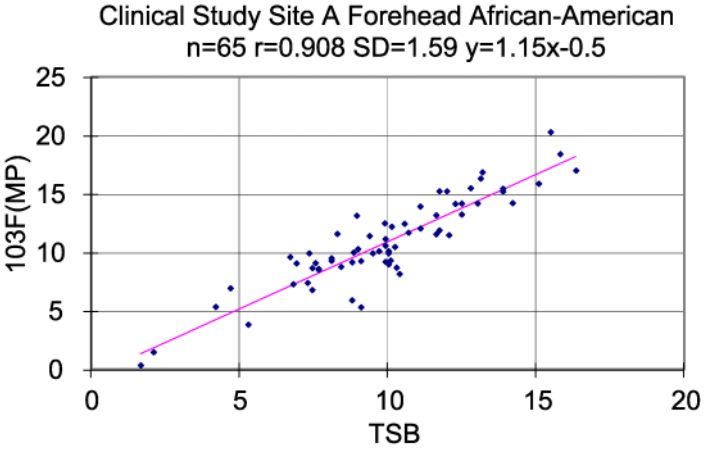
Graph 1 – Hospital Study Site A All Patients, Forehead



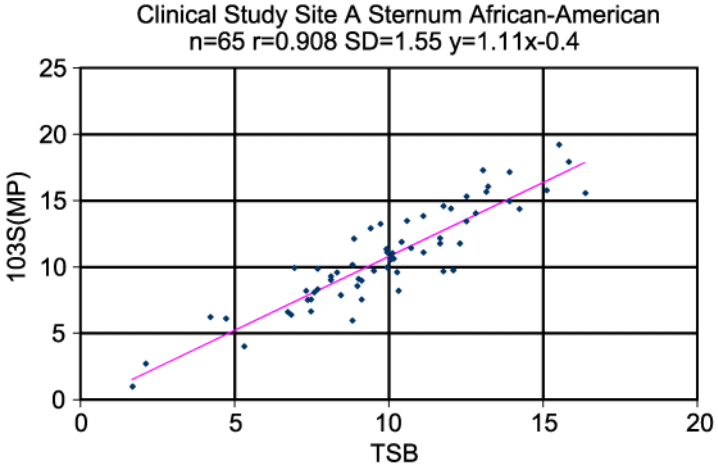
Graph 2 – ospital Study Site A All Patients, Sternum



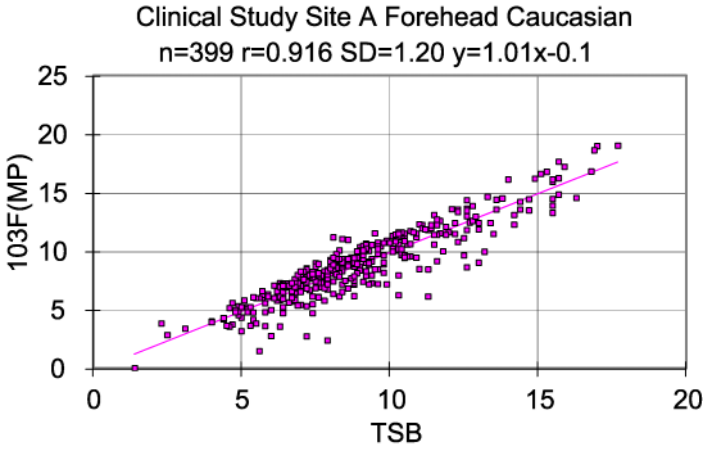
Graph 3 – Hospital Study Site A African-American Patients, Forehead



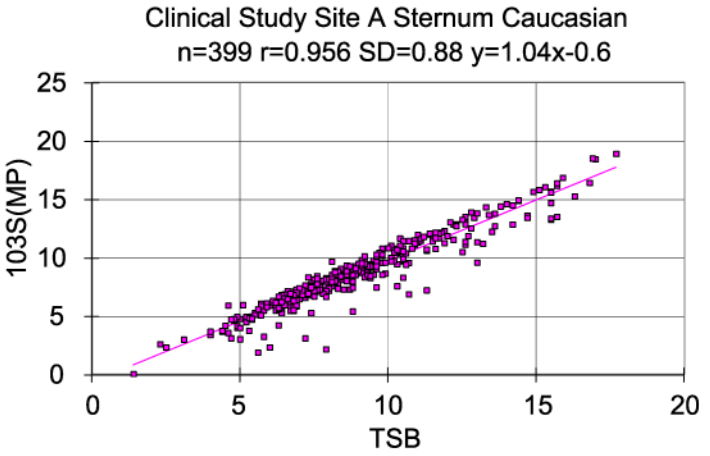
Graph 4 – Hospital Study Site A African-American Patients, Sternum



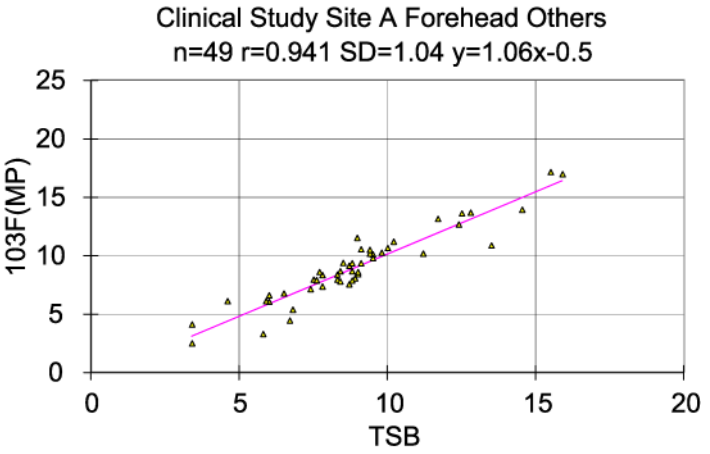
Graph 5 – Hospital Study Site A Caucasian Patients, Forehead



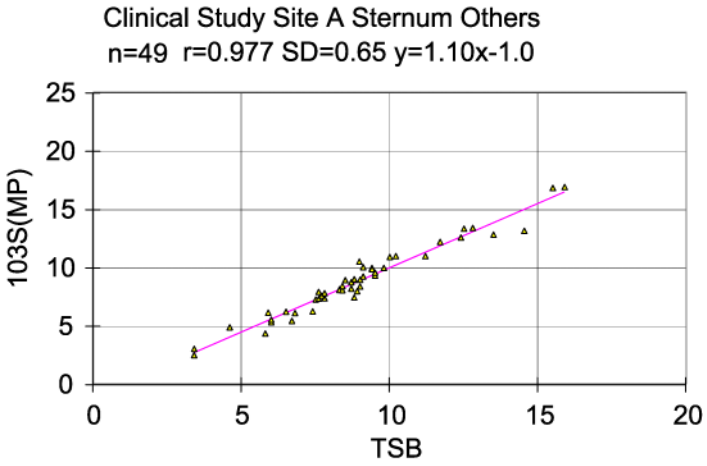
Graph 6 – Hospital Study Site A Causasian Patients, Sternum



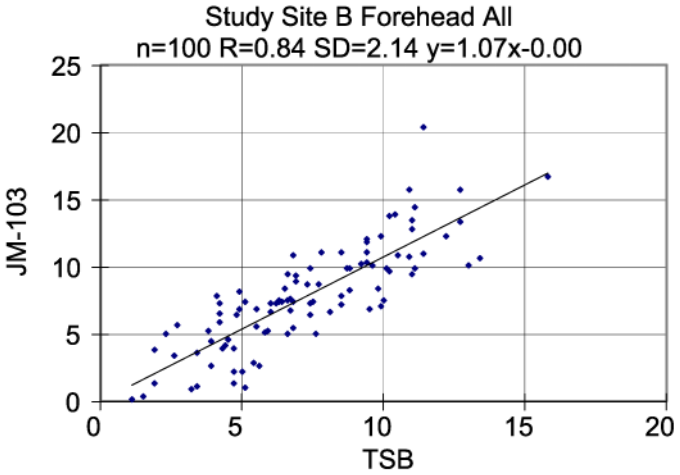
Graph 7 – Hospital Study Site A Other Patients, Forehead



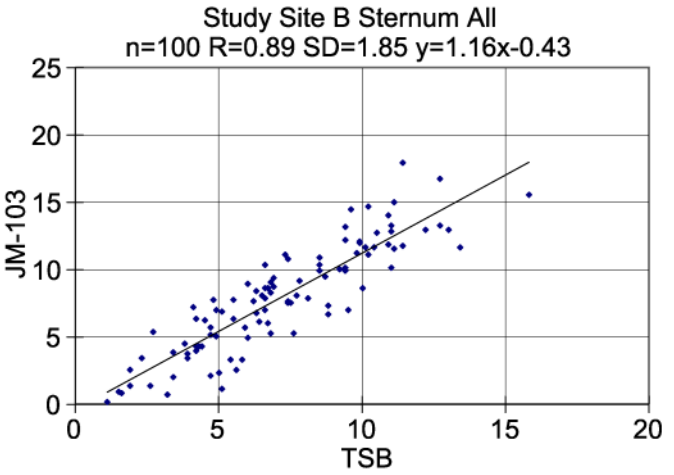
Graph 8 – Hospital Study Site A Other Patients, Sternum



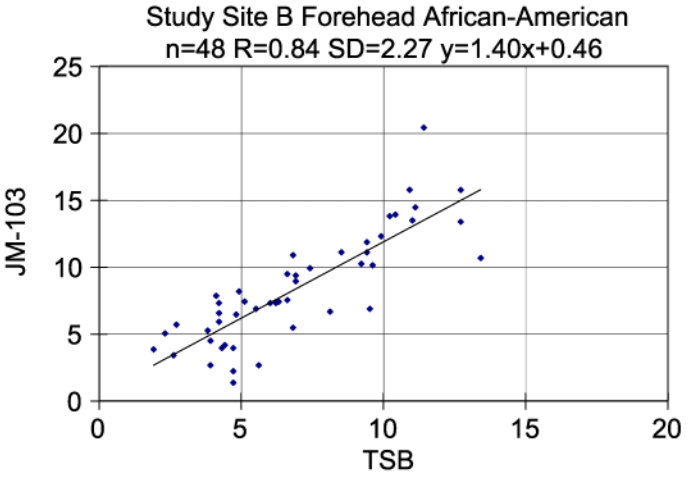
Graph 9 – Hospital Study Site B All Patients, Forehead



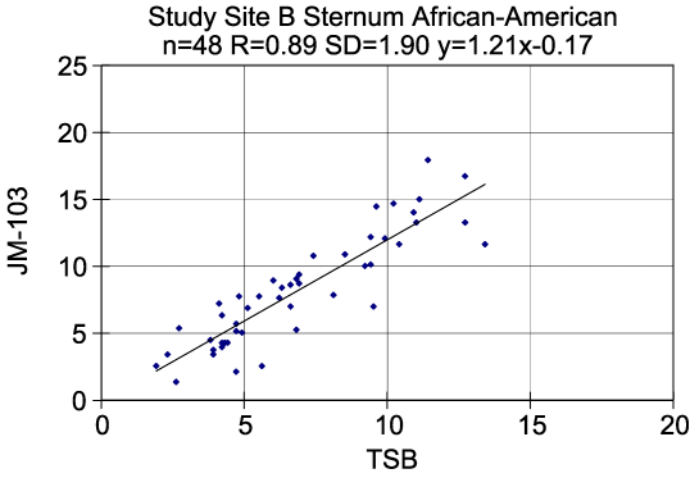
Graph 10 – Hospital Study Site B All Patients, Sternum



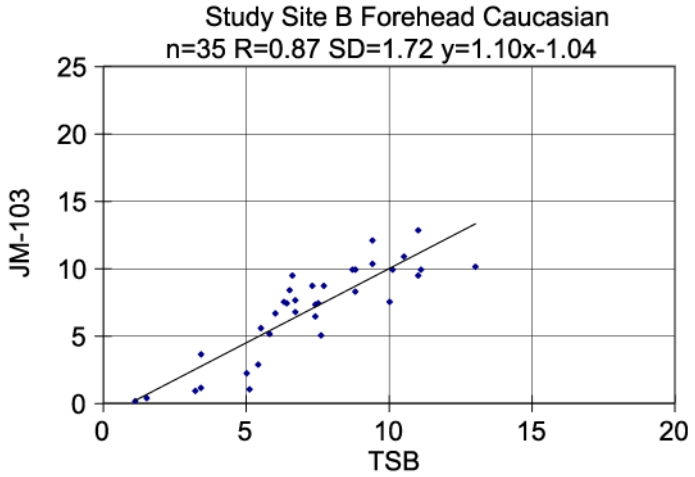
Graph 11– Hospital Study Site B African-American Patients, Forehead



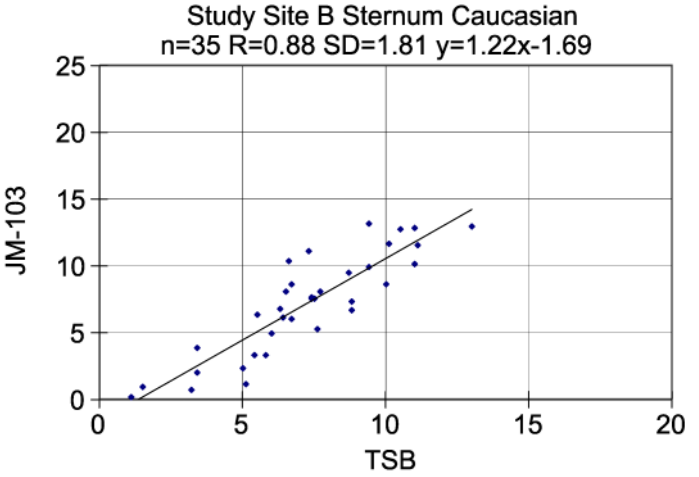
Graph 12 – Hospital Study Site B African-American Patients, Sternum



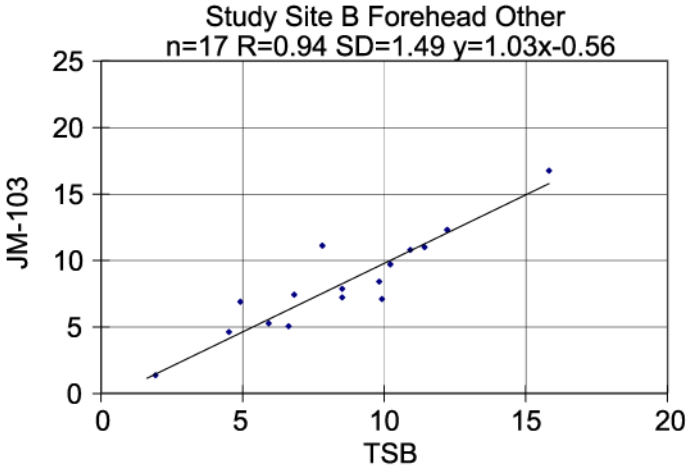
Graph 13 – Hospital Study Site B Caucasian Patients, Forehead



Graph 14 – Hospital Study Site B Causasian Patients, Sternum



Graph 15 – Hospital Study Site B Other Patients, Forehead



Graph 16 – Hospital Study Site B Other Patients, Sternum

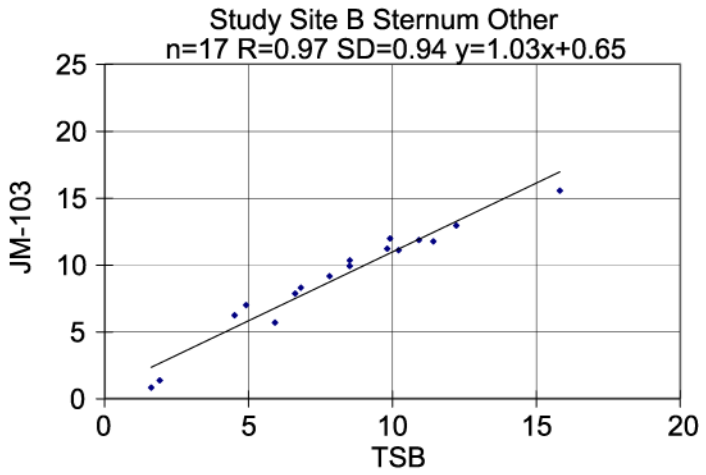
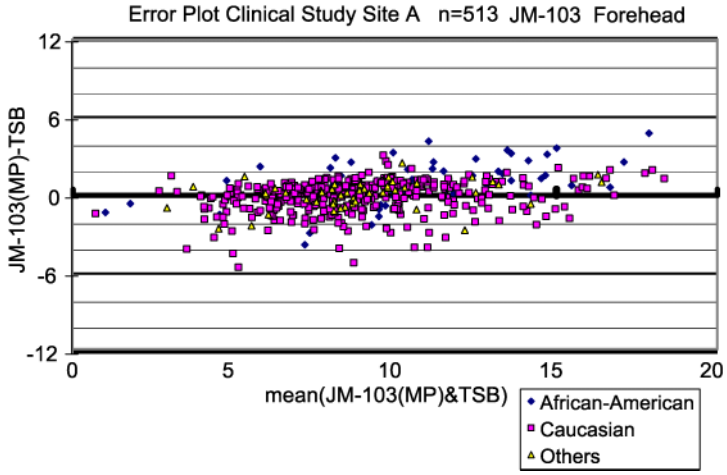


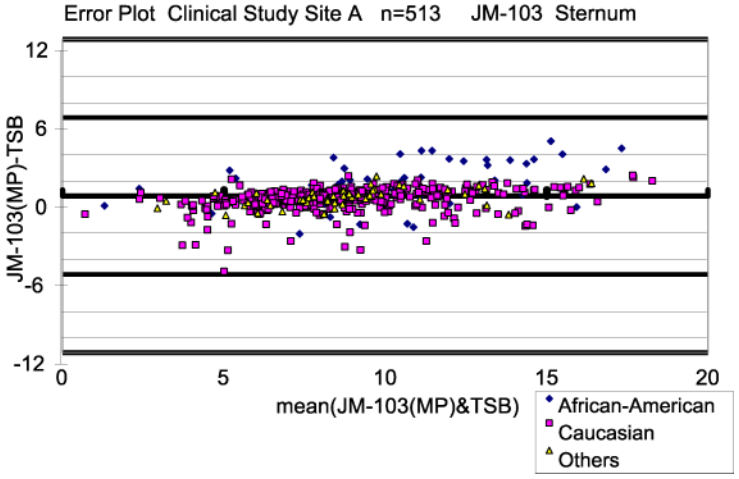
Table 1: Summary Table of Slope, Intercept, Standard Deviation, and Correlation Coefficients for Each Graph

Study Site / Patient Population	Slope	Intercept	Correlation Coefficient (r)	Standard Deviation (RMSE)
SITE A Forehead All (n=513)	1.05	-0.35	0.914	2.19
SITE A Sternum All (n=513)	1.07	-0.74	0.946	1.02
SITE A Forehead African American (n=65)	1.15	-0.5	0.908	1.59
SITE A Sternum African American (n=65)	1.11	-0.4	0.908	1.55
SITE A Forehead Caucasian (n=399)	1.01	-0.1	0.916	1.2
SITE A Sternum Caucasian (n=399)	1.04	-0.6	0.956	0.88
SITE A Forehead Other (n=49)	1.06	-0.5	0.941	1.04
SITE A Sternum Other (n=49)	1.10	-1.0	0.977	0.65
SITE B Forehead All (n=100)	1.07	-0.00	0.84	2.14
SITE B Sternum All (n=100)	1.16	-0.43	0.89	1.85
SITE B Forehead African American (n=48)	1.40	+0.46	0.84	2.27
SITE B Sternum African American (n=48)	1.21	-0.17	0.89	1.9
SITE B Forehead Caucasian (n=35)	1.10	-1.04	0.87	1.72
SITE B Sternum Caucasian (n=35)	1.22	-1.69	0.88	1.81
SITE B Forehead Other (17)	1.03	-0.56	0.94	1.49
SITE B Sternum Other (17)	1.03	0.65	0.97	0.94

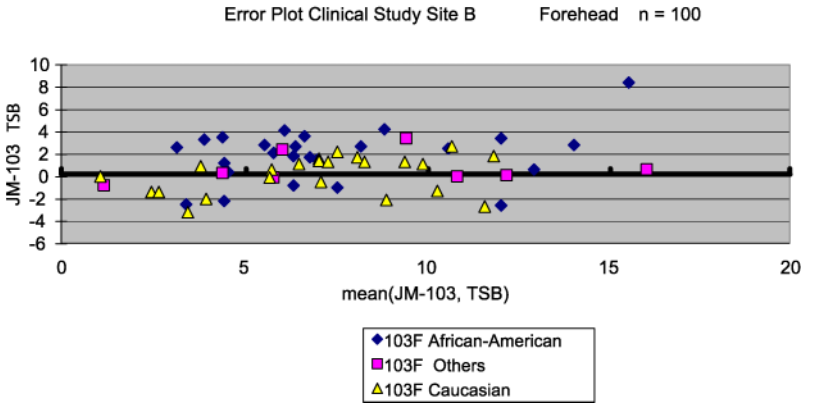
Graph 17 – Hospital Study Site A Error Plot, Forehead



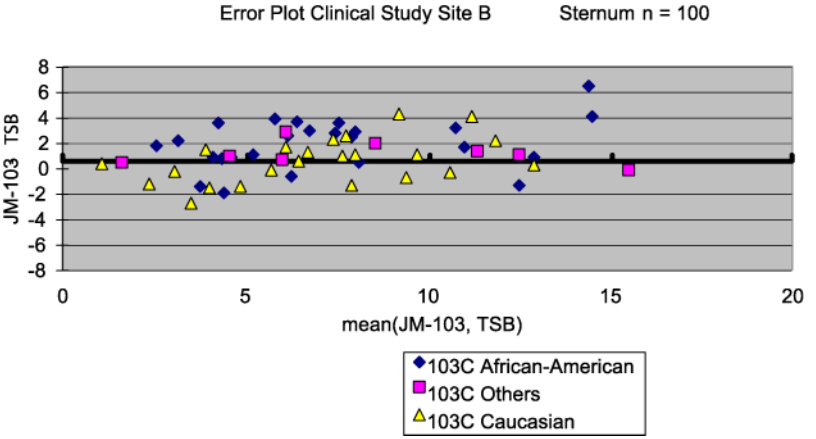
Graph 18 – Hospital Study Site A Error Plot, Sternum



Graph 19 – Hospital Study Site B Error Plot, Forehead



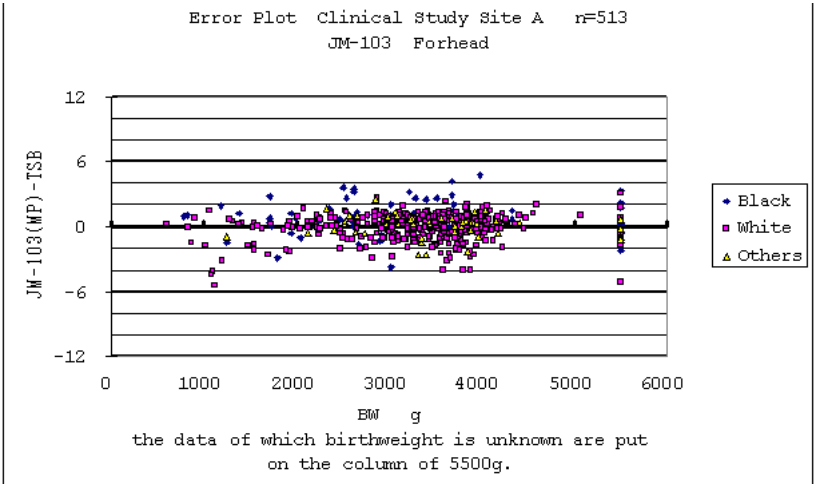
Graph 20 – Hospital Study Site B Error Plot, Sternum



Graph 21 – Infant Weight Distribution

Infant Weight (grams)	Hospital Study A	Hospital Study B
Up to 999	6	2
1000 - 1499	15	0
1500 - 1999	23	13
2000 - 2499	37	23
2500 - 2999	68	19
3000 - and up	337	43
Unknown	27	0
Total	513	100

Graph 22 – Hospital Study Site A Birthweight Error Plot, Forehead



Graph 23 – Hospital Study Site A Birthweight Error Plot, Sternum

Reproducibility

Reproducibility of the light output of the device was tested daily using the checker. The checker determines the intensity of the light output of the device. The accuracy of the device is determined by how well the detectors in the unit measure the returning light. The results of the device testing using the checker show that the device produced output within the required range over the course of both hospital studies.

Reproducibility testing in the patient population can be derived from the data taken in Hospital study site A. The reproducibility data is based on 467 babies. Three independent measurements were taken at each site, forehead and sternum. Each measurement was recorded, the mean and standard deviation computed and recorded. The average standard deviation for forehead and sternum measurements was 0.3 for both.

Table 2: Reproducibility Data

Body Site	Deviation Range	Deviation Mean	Deviation Median	Mean Estimated Bilirubin Measurement Range (mg/dL)
Sternum	0.0 - 2.2	0.3	0.3	0.8 - 18.5
Forehead	0.0 - 2.6	0.3	0.2	0.1 - 19.5

Conclusion

What the data presented shows is that the JM 103 estimated bilirubin concentration measurement correlates to the serum bilirubin measurements. This data supports the use of this non-invasive device along with other clinical indicators as an aid in the management of jaundice in the neonatal patient population.

NOTES:

Appendix B
Doctors' Office Data

Study Design

Studies were performed at 2 doctors' office sites comparing JM-103 Total Calculated Bilirubin (TcB) versus laboratory measured total serum bilirubin (TSB).

Selection Criteria

The ages of the infants in the study ranged from approximately 24 hours to 7-10 days, with a mean of 3 days (at site 1) and 5 days (at site 2). The test was performed on infants who were determined by their physician to require a serum bilirubin test.

Demographics of Patient Population

All patients meeting the above criteria were included in the study. The majority of babies were Caucasian or no skin tone noted (n=167) with a small number of reported ethnicity defined infants (n=34). The demographics of the patient population included Caucasian, African-American, and other.

The doctor's office study was composed of the following ethnic groups:

	TcB Range	Qty	Age
Caucasian	2.3-19.5	167	97≤72 hrs & 70≥72hrs
African American	4.9-17.3	13	6≤72 hrs & 7≥72hrs
Mid-Eastern	8.8 - 16.0	5	4≤72 hrs & 1≥72hrs
Indian	6.6- 17	5	4≤72 hrs & 1≥72hrs
Hispanic	7.6	1	
Asian	4.8-12.6	10	3≤72 hrs & 7≥72hrs

NOTE:
Doctor's Office #1: 83.5% Caucasian and 16.5% darker skin tone
Doctor's Office #2: 75% Caucasian and 25% darker skin tone

Exclusion Criteria

Infants requiring Exchange Transfusion or Phototherapy Initiated were not allowed in the study.

Sample Size

The doctor's office use trial studied 201 patients.

Measurement Selection

Estimated bilirubin measurements taken during the studies ranged from 2.3 to 19.5 mg/dL. No "Averaging of Readings" was used with the JM-103.

Body Sites Tested

All infants were measured at the sternum location ONLY .

Number of Doctors' Office Sites

For the doctor's office study, two sites were chosen for application of the device. Sample size was 201 patients.

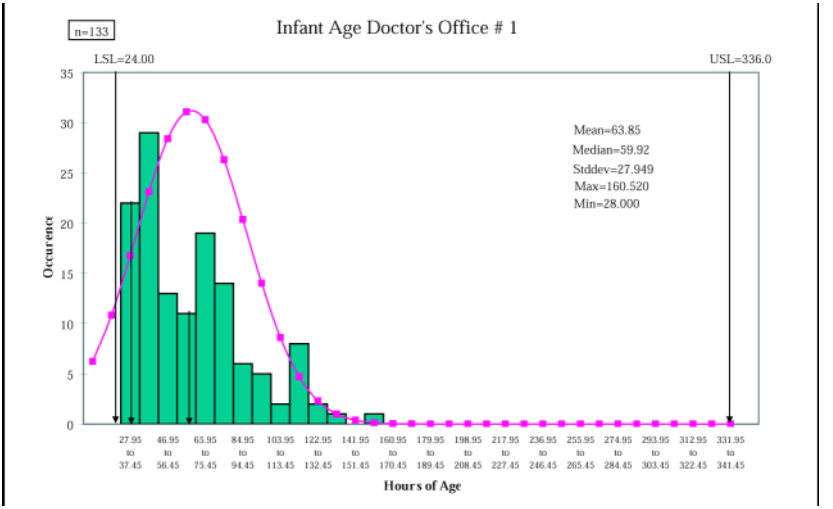
Performance Data

The data in the following sections is provided to demonstrate results of the JM-103 clinical studies, in comparison to total serum bilirubin. The JM-103 reports values over a range of 0-20 mg/dL estimated bilirubin. Although the Doctor's Office Study showed correlation of JM-103 to the TSB laboratory values, the relationship (bias) of the JM-103 to the TSB values was somewhat different than previously reported for hospital sites (as previously shown in Appendix A). This may be related to the ages of the infants in the doctor's office study and the difference in individual development. Therefore, please be aware that results at Doctors offices may differ from results at hospitals and may have more variability.

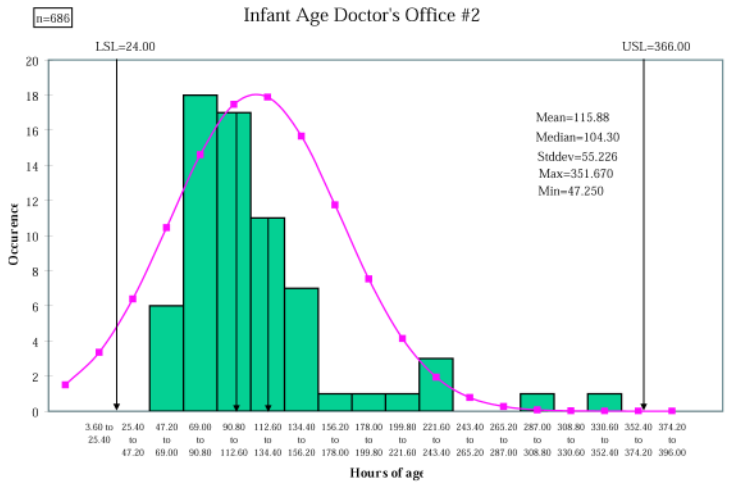
The reported data shows that 27% of the JM-103 measurements were higher than the Laboratory TSB and 71% were lower (2% were matched sets). Of the readings falling below the TSB value, 87% were within 3 Mg/dL of the TSB value. Those readings that reported above the TSB value 94% were within 3 Mg/dL of the reported TSB value. The largest error was a single 5.2 Mg/dL reading. The serum bilirubin measurements were taken using direct spectrophotometry and the Beakman-Colter Synchron LX-20by.

See Regression Analysis and infant age graphs below for data at the individual sites. A regression analysis is also provided on the total of 201 infants.

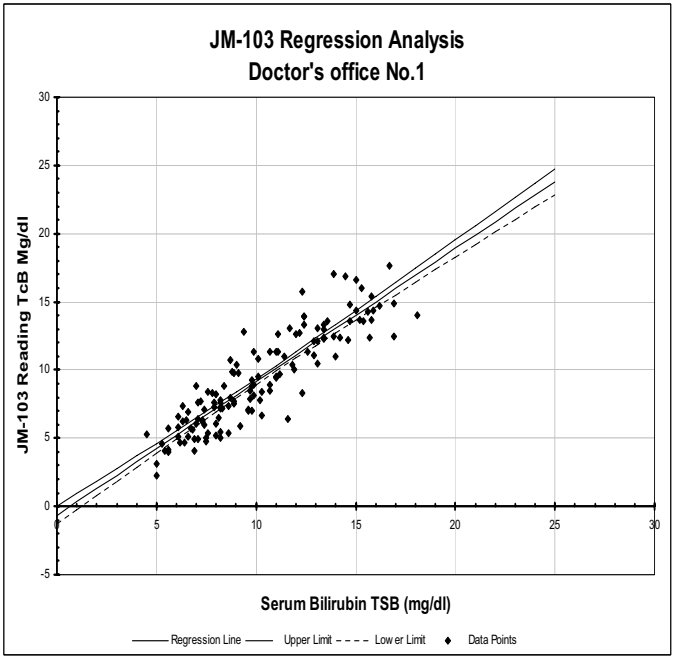
Graph 1 – Infant Age, Doctors' Office #1



Graph 2 – Infant Age, Doctors' Office #2



Graph 3 – Regression Analysis, Doctors' Office #1



Regression Analysis Statistics **Sample Size (n) = 133.**

Y = -0.636 + 0.977 X

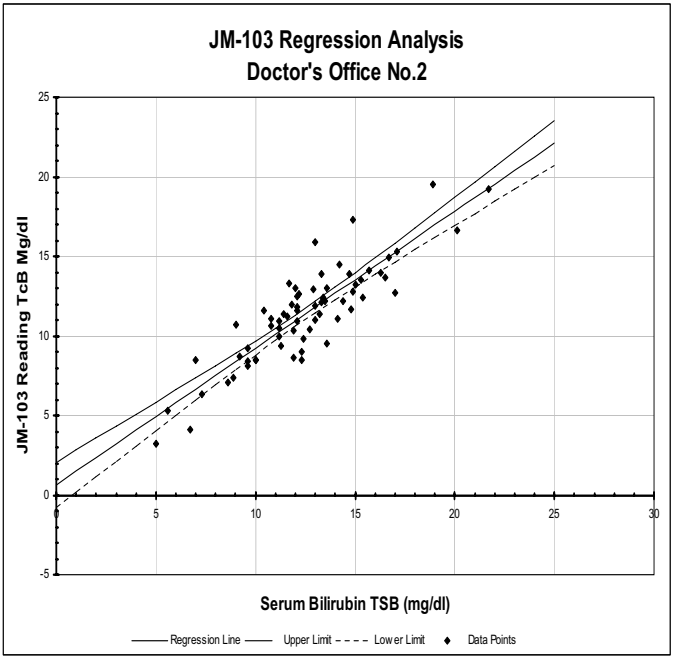
Root Mean Square Error (MSE) = 1.572

R-Square = 0.804

95% Confidence Interval (CI) for the Intercept = (-1.526, 0.254)

95% CI for the Slope = (0.894, 1.061)

Graph 4 – Regression Analysis, Doctors' Office #2



Regression Analysis Statistics **Sample Size = 68**

Y = 0.646 +0.859 X

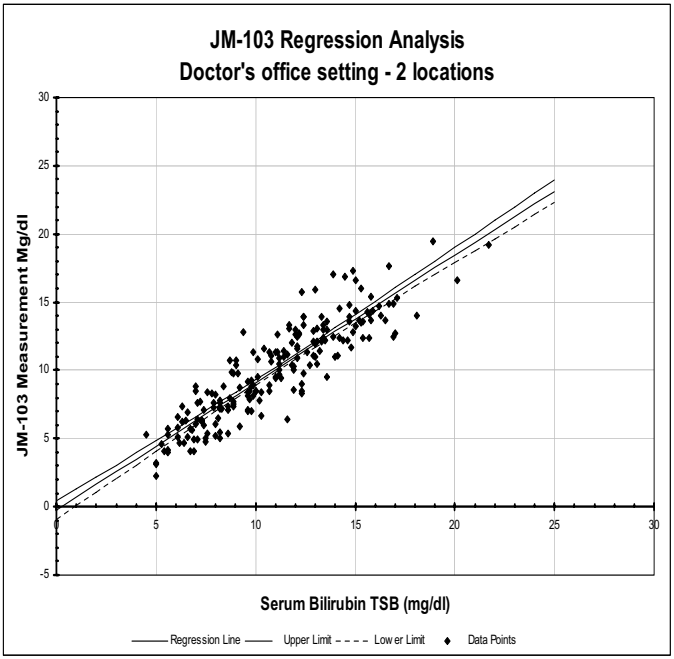
Root MSE = 1.475

R-Square = 0.769

95% CI for the Intercept = (-0.846, 2.138)

95% CI for the Slope = (0.743, 0.974)

Graph 5 – Regression Analysis, Doctors' Office Setting, 2 Locations



Regression Analysis Statistics **Sample Size = 201**

Y = 0.233 +0.934 X

Root MSE = 1.54

R-Square = 0.899

95% CI for the Intercept = (-0.233, 0.37)

95% CI for the Slope = (0.934, 0.032)

Conclusion

What the data presented shows is that the JM 103 estimated bilirubin concentration measurement correlates to the serum bilirubin measurements. This data supports the use of this non-invasive device along with other clinical indicators as a aid in the management of jaundice in the neonatal patient population.

Appendix C
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